United States Department of Health & Human Services

News Release

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FDA Announces Plans to Prohibit Sales of Dietary Supplements Containing Ephedra

Consumers Advised to Stop Using Ephedra Products Immediately

HHS Secretary Tommy G. Thompson today announced that the Food and Drug Administration (FDA) has issued a consumer alert on the safety of dietary supplements containing ephedra and has notified manufacturers of its intent to publish a final rule on dietary supplements containing ephedrine alkaloids. The rule will state that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury. The rule would have the effect of banning the sale of dietary supplements containing ephedrine alkaloids when it becomes effective, 60 days following publication.

"FDA will publish a final rule as soon as possible that will formalize its conclusions that dietary supplements containing ephedrine alkaloids present unreasonable risks to those who take them for any reason," Secretary Thompson said. "Today's action puts companies on notice of our intentions, and it tells consumers that the time to stop using ephedra products is now."

"We are taking action today to notify Americans about the unreasonable risk of ephedra as currently marketed in dietary supplements," said FDA Commissioner Mark B. McClellan, M.D., Ph.D. "Our action is based on diligent and thorough work by the agency as required by the challenging legal standard in the dietary supplement law. We worked hard to obtain and review all the available evidence about the risks and benefits of ephedra, including its pharmacology, studies of ephedra's safety and effectiveness, adverse event reports, and reviews by independent experts."

"By issuing these letters today, we're sending a strong and unambiguous signal about the safety of dietary supplement products containing ephedrine alkaloids. Consumers should stop buying and using ephedra products right away, and FDA will make sure consumers are protected by removing these products from the market as soon as the rule becomes effective."

According to the Federal Food, Drug, and Cosmetic Act, a dietary supplement product is adulterated if it or a dietary ingredient within it presents a significant or unreasonable risk of illness or injury under conditions of use suggested in the labeling or under ordinary conditions of use. Under the Dietary Supplement Health and Education Act of 1994, the FDA bears the burden of proof to show that a dietary supplement presents a significant or unreasonable risk to prevent it from being marketed; in contrast, for drugs that have similar pharmacologic properties to ephedra, manufacturers bear the burden of proof of showing that the drug is safe and effective before it can be marketed.

Ephedra, also called Ma huang, is a naturally occurring substance derived from botanicals. Its principal active ingredient is ephedrine, which when chemically synthesized is regulated as a drug. In recent years ephedra products have been extensively promoted for use to aid weight loss, enhance sports performance, and increase energy.

FDA's concerns about dietary supplements containing ephedra arise in part from ephedra's mechanism of action

in the body. Ephedra is an adrenaline-like stimulant that can have potentially dangerous effects on the heart. FDA's evaluation also reflects the available studies of the health effects of ephedra. This includes many studies reviewed by the RAND Corporation, which found little evidence for effectiveness other than for short-term weight loss, as well as evidence suggesting safety risks. Other recent studies have also confirmed that ephedra use raises blood pressure and otherwise stresses the circulatory system, effects that have been conclusively linked to significant and substantial adverse health effects like heart problems and strokes.

FDA's notification reflects the agency's recent comprehensive evaluation of the science as well as a public comment period intended to cap years of debate about the risks and safety of ephedra in dietary supplements. In 1997, FDA first proposed a rule on dietary supplements containing ephedra including requiring a warning statement on these products. FDA modified this proposed rule in 2000, and last February the agency announced a series of comprehensive actions designed to protect Americans from the potentially serious risks of dietary supplements containing ephedra. To solicit comments on new evidence about ephedra as well as on a proposed warning statement, last February's actions included publishing a Federal Register notice outlining FDA's concerns and reopening the comment period.

Following publication of this notice, FDA received and reviewed tens of thousands of comments. The agency has also reviewed a comprehensive RAND Corporation report on the data on ephedra and a series of adverse event reports that it was unable to obtain more quickly because under the Dietary Supplement Health and Education Act such adverse event reports are not required to be submitted to FDA.

"We are going to issue a rule that clarifies and applies a legal standard that that has never been used before. Using the challenging standard provided under the law, we have done all we can to make sure our regulatory action will succeed," said Dr. McClellan.

FDA has sent 62 letters to firms marketing dietary supplements containing ephedra and ephedrine alkaloids alerting them of this future rule.

While working on the forthcoming rule, FDA has been actively protecting the public health through a series of high-profile enforcement actions aimed at addressing the public health danger. Dietary supplement enforcement actions include inspections that resulted in voluntary compliance, voluntary recalls, warning letters, seizures and injunctions, criminal enforcement and joint enforcement actions with the Federal Trade Commission and the Department of Justice. In conjunction with FDA's actions to date, classes of ephedra products have already been removed from the market (for example, many products marketed for enhancing sports performance), the demand for ephedra products has declined significantly, and many companies have already ceased marketing. (More detail on these actions can be found at http://www.fda.gov/ola/2003/dietarysupplements1028.html).

Additional materials relating to today's announcement are available online at www.fda.gov.

Additional materials:
FDA letter: http://www.fda.gov/oc/initiatives/ephedra/december2003/warningltr.html
List of companies receiving letter: http://www.fda.gov/oc/initiatives/ephedra/december2003/letterslist.html
2/03 press release: http://www.fda.gov/bbs/topics/NEWS/2003/NEW00875.html
Consumer Advisory: http://www.fda.gov/oc/initiatives/ephedra/december2003/advisory.html

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Note: All HHS press releases, fact sheets and other press materials are available at *http://www.hhs.gov/news*.

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